

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office on March 23, 2020.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Sections 4001.1 and 4005 of the Business and Professions Code authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 141, 490, 4022.5, 4022.6, 4022.7, 4036, 4038, 4053, 4112, 4115, 4161, 4200.5, 4202, 4207, 4231, 4300, 4301, 4301.5, 4302, 4303, 4303.1, 4311, 4316, and 4400 of the Business and Professions Code and section 11105 of the Penal Code.

Informative Digest/Policy Statement Overview

The California State Board of Pharmacy (board) proposes to amend or repeal the regulatory language of 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 to consolidate all board license types to ensure that the board's regulations remain efficient and consistently applied to all license types, even those that may be created in the future.

Existing pharmacy law specifies that protection of the public is the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions and generally authorizes the board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. Additionally, existing pharmacy law at 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 establish the license renewal requirements for board licensees. These regulatory sections are necessary to provide clarity to the regulated public with respect to the requirements and criteria used by the board to deem an application for renewal complete.

As currently written, the regulation sections require frequent amendments to incorporate each new licensing program as they are established. Amending regulations is a time intensive process and the board has not been able to update the regulation as frequently as necessary. Since 2014, the board's regulatory jurisdiction has increased in size. In 2018 alone, the board's licensing types grew from 25 to 39. This proposal will simplify the regulatory language and consolidate the license types into two categories: (1) a premises or facility license and (2) an individual license, with an exception for the pharmacist and advanced practice pharmacist licensee, as these licensing programs have specialized continuing education requirements. Consolidating the regulations text to only two categories will provide clarity to the regulated public by increasing the readability of the regulations and ensure consistent application of the renewal requirements.

Additionally, as currently written, the regulations do not require all premises or facility license types to report disciplinary action taken by other government agencies to the board; this is only required of nonresident pharmacies and nonresident wholesalers. The proposed regulations would allow the board a mechanism to identify such discipline for all premises or facility license types. If a licensee has been disciplined by another agency, the board must be made aware of this discipline in order to investigate and ensure that the licensee does not pose a risk to the safety of California residents by continuing to operate.

Anticipated Benefits of Proposal

This regulatory proposal benefits California residents because the proposed regulation will simplify the regulatory language which will provide clarity to the regulated public. A premises/facility cannot operate with an expired license and an individual cannot work with an expired license. These regulations will ensure that the requirements for a complete renewal application are clearly specified based on the license type (premises/facility or individual). This will help to ensure that licensees are submitting complete applications, which will allow for the timely renewal of licenses. Renewing licenses timely ensures that individuals can continue to work and premises/facilities can continue to distribute and/or furnish prescription medication to California residents. Additionally, the disclosure of discipline by all premises or facility licensees will allow the board to investigate the disciplinary action and ensure that the licensees are operating in accordance with pharmacy law, which will ensure the health and welfare of California residents. Lastly, the proposed action will increase the board's efficiency by eliminating the need to prepare a regular rulemaking action each time a new license type is created.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: There will be minor workload costs to the board, which are absorbable with the board's budget.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees including the ability of California businesses to compete with businesses in other states. This determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, the proposed regulation will simplify the regulatory language, thereby providing clarity and consistency to the regulated public with respect to the requirements and criteria used by the board to deem an application of renewal complete. The proposed regulations require all premises or facility licensees to report discipline by another government agency at the time of the license renewal; however, this is done by marking an indicator on the application for renewal and will not impose an economic or fiscal impact on the licensee.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

Effect on Small Business:

While the board does not have nor does it maintain data to define if any of its licensees (pharmacies) are a "small business" as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. This determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, the proposed regulation will simplify

the regulatory language, thereby providing clarity and consistency to the regulated public with respect to the requirements and criteria used by the board to deem an application of renewal complete. The proposal requires all premises or facility licensees to report discipline by another government agency at the time of the license renewal; however, this is done by marking an indicator on the application for renewal and will not impose an economic or fiscal impact on the licensee.

Results of Economic Impact Assessment/Analysis:

The board concludes that this regulatory proposal will have the following effects:

- (1) It will not create or eliminate any jobs within California;
- (2) It will not create new, or eliminate existing, businesses in California; and
- (3) It will not expand businesses currently doing business within the state.

As the board's licensing program authority has increased, the board has not been able to update these regulations at the same pace. The proposed regulations provide clarity to all licensees with respect to the requirements necessary for a renewal to be deemed complete by the board and will ensure consistent application of the renewal requirements. While this may allow a business or individual to renew their license timely, the regulatory proposal does not actually create the business or the job.

Benefits of Regulation:

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation will simplify the regulatory language which will provide clarity to the regulated public. A premises/facility cannot operate with an expired license and an individual cannot work with an expired license. These regulations will ensure that the requirements for a complete renewal application are clearly specified based on the license type (premises/facility or individual). This will help to ensure that licensees are submitting complete applications, which will allow for the timely renewal of licenses. Renewing licenses timely ensures that individuals can continue to work and premises/facilities can continue to distribute and/or furnish prescription medication to California residents. If a business is able to continue services, it benefits the health and welfare of California residents by providing continued access to pharmacy related care. Additionally, it will ensure that the board is aware of any disciplinary action taken by other government agencies against a board licensee. This disclosure will allow the board to investigate the disciplinary action and ensure that the licensees are operating in accordance with pharmacy law, which will ensure the health and welfare of California residents. Lastly, the proposed action will increase the board's efficiency. The proposed regulation does not affect worker safety or the state's environment because it does not involve these matters.

Consideration of Alternatives

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations during the written comment period at the address listed for the Contact Person.

Initial Statement of Reasons and Information

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has made available all the information upon which the proposal is based.

Text of Proposal

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <http://www.pharmacy.ca.gov>.

Availability and Location of the Final Statement of Reasons and Rulemaking File

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

Contact Person

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Lori Martinez
Address: 2720 Gateway Oaks Dr., Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3078
Fax No.: (916) 574-8618
E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Debbie Damoth
Address: 2720 Gateway Oaks Dr., Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3090
Fax No.: (916) 574-8618
E-Mail Address: Debbie.Damoth@dca.ca.gov

Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website:
www.pharmacy.ca.gov.